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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,866	04/11/2005	John-Olov Jansson	JANSSON7	2241

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EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,866	JANSSON, JOHN-OLOV	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14,15,18,20,22,27,28,30 and 38-40* is/are pending in the application.

4a) Of the above claim(s) *10,18,20,39 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,14,15,22,27,28,30 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the response filed 8/21/07, claims 1, 15, 22 have been amended, and claims 39-40 added. Claims 1-10, 14, 15, 18, 20, 22, 27, 28, 30, 38-40 remain pending.

✧

Newly submitted claims 39-40 are directed to an invention that is independent or distinct from the invention originally claimed. The claims were drawn to a method of treating disorders in a subject who had undergone gastrectomy, and not a method of treating disorders in a subject who had undergone both gastrectomy and vagotomy. These surgical procedures could be viewed as a "combination/subcombination" relationship.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Claims 10, 18, 20, 39, 40 are withdrawn from consideration; claims 1-9, 14, 15, 22, 27, 28, 30, 38 are examined in this Office action.

✧

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his

invention.

Claims 1-9, 14, 15, 22, 27, 28, 30, 38 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As applicants have asserted, Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) supports the proposition that it is impossible to perform a gastrectomy without also performing a vagotomy, and that once a vagotomy is performed, ghrelin loses all activity. Given applicants assertion in this regard, it follows therefrom that all claims lack enablement.

A matter separate from the foregoing concerns claim 38. This claim recites the term "prophylactically effective". Even if it is true that ghrelin can mitigate loss of body weight, or that ghrelin can mitigate the state of cachexia, it does not follow therefrom that outright prevention can be achieved.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or

unpredictability of the art, and breadth of the claims. In support of their assertion that they can prevent loss of body weight, loss of body fat, loss of appetite, or development of cachexia, applicants have (pages 47-48) administered a growth hormone secretagogue an unspecified number of rats. Applicants have asserted that as a result of (administration of) this compound, they could detect a slight increase in the amount of fat present in one of the rats. In all likelihood, this increase in fat was not statistically significant. Moreover, this would not demonstrate that loss of body weight, loss of body fat, loss of appetite, or development of cachexia can be prevented, even if the claims were drawn to methods of using growth hormone secretagogues.

Applicants have argued that other examiners have abstained from rejecting this term (prophylaxis), and that if one examiner abstains from imposing a rejection in a particular situation, all other examiners who follow that examiner are obligated to do the same. According to this line of reasoning, all Supreme Court decisions would have to be decided by a 9-0 vote. The reality is that one examiner is not bound by decisions made by other examiners. And even if they were, the next question would be, who should follow whom? Should it be the examiners who have chosen to reject, or the examiners who have chosen to abstain from rejection?

Applicants have also argued that one could consult a dictionary or encyclopedia. The Webster's 9th edition recites that one meaning of the term "prophylactic" is preventative; the

term "prevent", in turn, can mean "to keep from happening". Notwithstanding the foregoing examiner would agree that the term "prophylactic" encompasses the possibility that absolute prevention is not achieved. But the term does also encompass the possibility that it is. If there is descriptive support for it, applicants could use an alternative terminology which is consistent with the meaning that they are ascribing to "prophylactic".

As matters currently stand, "undue experimentation" would be required to practice the claimed invention.

✧

Claim 38 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is drawn to a method of treating disorders in a subject who has not actually undergone gastrectomy. At the same time, the claim requires that the disorder that is being treated be attributable to gastrectomy. Thus, there is a contradiction; which limitation controls?

✧

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented

and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

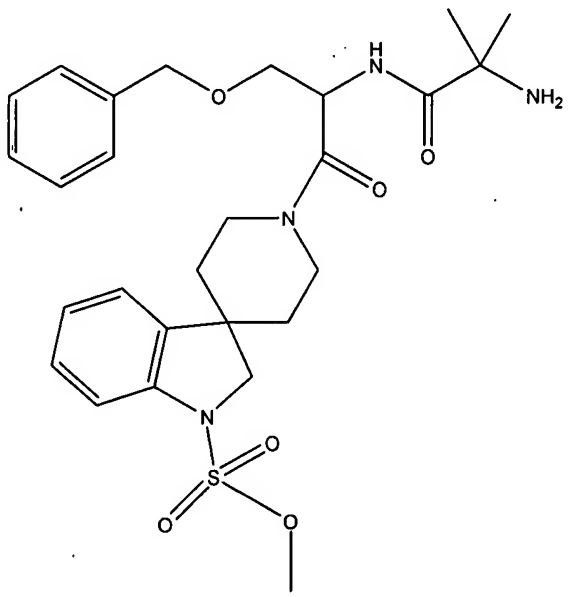
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 14, 15, 22, 27, 28, 30, 38 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or (ii) Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001).

As indicated previously, each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite. Accordingly, it would have been obvious to administer ghrelin to reverse the adverse effects of weight loss caused by the gastrectomy. In response to the foregoing, applicants have argued that Asakwa states somewhere that if a surgeon were to deliberately perform a vagotomy, ghrelin will be rendered ineffective. Applicants have declined to identify the passage where this

may be found. The examiner asserts that this is not what Asakawa states (applicants, are, of course, invited to point to the relevant passage of text). Furthermore, this ground of rejection does not depend on Asakawa. Thus, one of the various reasons why this ground of rejection remains justified is that if Asakwa is not considered, applicants traversal disintegrates.

Moreover, applicants have yet to demonstrate any "unexpected results". What applicants have done (pages 47-48) is to administer the following compound to an unspecified number of rats:



Applicants have asserted that as a result of (administration of) this compound, they could detect a slight increase in the amount of fat present in one of the rats. Perhaps

the increase in weight of the fat was 1%, perhaps it was 0.01%. One can only speculate. Perhaps the increase in fat weight was statistically significant, and perhaps not. Moreover, the compound that was administered is a growth hormone secretagogue (Patchett, *Proc Natl Acad Sci* 92, 7001, 1995). Perhaps one can argue that this is an "analog" of ghrelin, but at best, it exists only at the periphery of the invention. Certainly, applicants have presented nothing that would qualify as an "unexpected result" insofar as the peptides of claim 7 or 9 is concerned.

The claims remain prima facia obvious.

✧

Claims 1-9, 38 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or (ii) Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) further in view of Kojima,M. (Nature 402 (6762), 656-660, 1999).

As indicated above, each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite. Kojima provides the sequence of ghrelin.

Thus, the claims remain obvious.

✧

Claims 1-9, 38 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or (ii) Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) further in view of Hosoda,H. (*J. Biol. Chem.* **278**(1), 64-70, 2003)

As indicated above, each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite.

Thus, the claims remain obvious.

✧

Claim 38 is rejected under 35 U.S.C. §103 as being unpatentable over Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001).

As indicated previously, each of Wren and Asakawa disclose that ghrelin stimulates appetite.

Claim 38 encompasses a method of inhibiting loss of appetite in a subject who has not

actually undergone gastrectomy. Claim 38 requires only that the person have the intent to have the surgery done at some point in the future. The "future" could be 2 weeks, or the future could be 20 years hence. As such, the phrase "prior to gastrectomization" exerts little impact. As it happens, a persons' intent with regard to elective surgery has no bearing on his (or her) physiological response to a peptide.

Thus, the claim is rendered obvious.

✧

Claim 38 is rejected under 35 U.S.C. §103 as being unpatentable over Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) further in view of Hosoda,H. (*J. Biol. Chem.* **278**(1), 64-70, 2003)

The arguments presented above (the §103 over Wren or Asakawa) apply here as well.

✧

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE

DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

- Reference "CB" was stricken from the IDS. The record should make it clear that a translation was provided only for claims 1-7.

- Reference "CE" was stricken from the IDS. The record should make it clear that a translation was provided only for the abstract. The following format could be used:

  Abstract of Tanikawa (*Adv Med Sci* 155 623, 1990)

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER